

# Exhibit 4

February 15, 2022

## **TEMPORARY DATA INACCURACIES IN THE DEFENSE MEDICAL EPIDEMIOLOGY DATABASE**

### **BLUF:**

- Department of Defense (DoD) officials detected and resolved a programming error in the Defense Medical Epidemiology Database (DMED) that had caused the database to inaccurately suggest that outpatient medical encounters for some conditions had significantly increased in 2021. In January 2022, Department officials found that data in DMED covering the years 2016 – 2020 had been corrupted during an August 2021 server migration, showing only 10% of the true number of medical encounters for that period. The corrupted data made it impossible to accurately compare medical encounter rates across the Military Health System (MHS) from 2021 to the 2016 - 2020 period because researchers could not correctly baseline their observations. In January 2022, Department officials resolved the programming error and adopted new auditing procedures for future server migrations. The accurate changes in medical encounters for the reported diagnoses are provided below.

### **ISSUE:**

- On January 26, 2022, an opinion article was published suggesting that there was a large increase in outpatient medical encounters for various conditions among active component Service members when comparing the 2016-2020 annual average to 2021.
- Percent increases cited in the article included neurological issues (1,000%), myocardial infarction (269%), Bell's palsy (291%), congenital malformations (156%), female infertility (471%), and pulmonary embolisms (467%).
- The article suggested that these increases were due to adverse effects of COVID-19 vaccination.
- The authors used the DMED as their data source. The DMED is maintained by the Armed Forces Health Surveillance Division (AFHSD) in the Defense Health Agency.

### **BACKGROUND:**

- DMED, developed in 1997, is a web-based tool to query de-identified active component personnel and medical event data contained within the Defense Medical Surveillance System (DMSS). It contains no personally identifiable information and no protected health information.
- DMSS is AFHSD's relational database that is used to conduct epidemiologic surveillance on Service members and is the underlying data source for DMED.
- DMED is available via remote access to authorized users, including U.S. military medical providers, epidemiologists, medical researchers, safety officers or medical operations/clinical support.
- The purpose of DMED is to provide quick access to summarized epidemiologic data for surveying health conditions in Service members. The ability to make inferences from the data using the available preset queries is very limited.
- DMED is more useful as a tool to generate questions rather than a tool to answer them. To address specific questions on Service members' health, a more thorough analysis is required.

**DISCUSSION:**

- On January 26th, the AFHSD of the Defense Health Agency created and preserved a full backup of the DMED.
- As part of a January 27, 2022 review and analysis, AFHSD found that the data in DMED was corrupt for the years 2016-2020 when accessed after September 2021. The DMED database is “refreshed” or re-created each month to stay in sync with DMSS. This refresh process was investigated and found to be the cause of the error.
- The review and analysis revealed that DMSS data contained approximately 22 million outpatient encounters for active component Service members for 2020. The same query found only 2 million outpatient encounters for active component Service members in DMED.
- The data for years 2016 through 2020 contained only approximately 10% of the true number of outpatient medical encounters for that period, which created an inaccurate appearance that diagnoses for medical conditions increased when compared to previous years.
- On January 28, 2022, AFHSD replicated the user queries of DMED that were referenced in recent media coverage, using accurate DMSS data, and found the following percent changes in outpatient medical encounters counts among Active Duty Service members when comparing the 2016-2020 annual average to 2021: Neurological issues (3.0%), myocardial infarction (1.4%), Bell’s palsy (0.8%), congenital malformations (1.0%), female infertility (-6.5%), and pulmonary embolisms (37.5%). These are changes in the number of health care encounters for that particular condition, not changes in the prevalence of the condition.
- Counts of health care encounters are not representative of new cases of these diagnoses; they are a measure of the workload for the health system regarding provision of care associated with these diagnoses. Counts of health care encounters cannot be used as a proxy for the prevalence of disease.
- On February 2, 2022, AFHSD replicated the queries to validate data post-DMED corrective actions. Updated results include the percent change in health encounters comparing available 2021 data to 2016-2020.

<b>Medical Encounter Conditions</b>	<b>Reported change to number of health care encounters (2021 compared to last 5 years) using erroneous data</b>	<b>DMED query results for change to number of health care encounters (2021 compared to last 5 years) following data correction</b>
Diseases of the nervous system	1,048% increase	5.7% decrease
Hypertension	2,181% increase	1.9% increase
Tachycardia	302% increase	8.3% decrease
Testicular cancer	369% increase	3% increase
Ovarian dysfunction	437% increase	23.9% increase
Migraines	452% increase	1.6% increase
Pulmonary embolism	468% increase	25.4% increase

Female infertility	472% increase	13.2% decrease
Malignant neoplasms of thyroid and other endocrine glands	474% increase	16.1% decrease
Breast cancer	487% increase	1.1% increase
Demyelinating	487% increase	17.7% decrease
Guillain-Barre syndrome	551% increase	17.2% decrease
Malignant neoplasms of digestive organs	624% increase	0.2% increase
Multiple sclerosis	680% increase	16.7% decrease
Malignant neoplasms of esophagus	894% increase	27.8% increase

- The DMED data queries presented in the tables above reflect health care utilization and include all health encounters with the related diagnostic codes. These queries capture disease screening, follow-up and even miscoded appointments for hospital stays and outpatient appointments. To determine the trend in any of the listed disease categories, DMSS must be used to refine the query and define criteria for the diagnoses (pre-existing versus new), as well the accuracy of the diagnoses with the inclusion of additional data such as procedures, medication, or related laboratory results.
- DMED is recreated every month using DMSS data, which relies on continuously refreshed medial administrative and personnel data. Fluctuations occur in the total number of personnel and health encounters. Because the denominator changes and does not remain static, rates should be used for comparison across time periods, not the number of encounters.

#### **ROOT CAUSE ANALYSIS:**

- On January 29, 2022, a programming logic error was discovered in the code used to create some of the DMED summary data tables.
- The DMED monthly refresh procedure was updated in August 2021 following a planned server migration. The programming error was introduced at that time and has affected DMED data since September 2021.
- Not all of the DMED tables were affected by the logic error and not all DMED queries were affected by the corrupt data. Quality control measures were focused on larger, more detailed DMED tables and failed to detect this error in the smaller aggregate data tables. Additional quality control measures are being implemented to mitigate the risk of this logic error occurring again.

#### **SUMMARY:**

- AFHSD will continue to support data requests using DMSS, including support to the Immunization Healthcare Division in its efforts to identify Active Duty military personnel who have encountered adverse health events after receiving COVID-19 vaccination.
- As of January 29, 2022, the programming logic error has been corrected and tested in a development environment. DMED data was re-generated and access to DMED data via the online application was restored on January 30, 2022.

- The data displayed in DMED has undergone extensive quality assurance testing by multiple analysts and has been found to be consistent with the source data in the DMSS.
- Quality control measures will be expanded to include all of the DMED tables and columns to prevent future occurrences of inaccurate data appearing in DMED. A second functional quality control check will be implemented following each monthly release of DMED data.